

Appl. No. 09/822,585
Amdt. Dated August 14, 2003
Reply to Office Action of March 18, 2003

Docket No. MGH-004BUS

R E M A R K S

The above-identified patent application has been amended and Applicants respectfully request that the Examiner reconsider and again examine the claims as amended.

Claims 1-30 and 39-43 are pending in the present application. Claims 1-30 stand rejected. Claims 1, 2, 5, 7, 9-11, 14, 18, 22, 26, 29 and 30 are herein amended. Claims 31-38 are cancelled. Claims 39- 44 are herein added.

In accordance with the revised provisions of 37 C.F.R. §1.121(c) as set forth in Official Gazette Notices: 25 February 2003, a marked up version of the amended claims is provided hereinabove.

The Examiner requested a copy of all the foreign documents and articles in the Information Disclosure Statement (IDS) filed on September 20, 2001. The foreign documents and articles total over 300 documents, and providing another set to the Examiner would be a considerable burden. Enclosed herewith is a copy of the return postcard from the PTO showing that the PTO received the documents on September 20, 2001. Applicants respectfully request the PTO to conduct a search for the box of documents. In the event the documents cannot be located, then Applicants request the Examiner to telephone the undersigned attorney, and another copy of the documents will be provided to the PTO.

The Examiner objected to claims 5-7, 18 and 30 due to certain informalities. Claims 5-7, 18 and 30 have been amended to correct the informalities listed by the Examiner. In particular: in claim 5, the full names of all brain regions have been provided; in claim 7 the names of all neuro imaging devices have been provided; and in claim 30, the numerical designation of the claim has been provided.

Claim 6 did not appear to contain any informalities of the type referred to by the

Examiner and thus no changes have been made to claim 6.

With respect to claim 18, the Examiner requested that the full name for the R index and L index be added. Applicants would like to respectfully point out that while "R" corresponds to right and "L" corresponds to left, the terms "R index" and "L index" are the full names for these indices. Thus, Applicants have not made any change to claim 18 with respect to these names.

Accordingly, in view of the above amendments and remarks, Applicants respectfully request that the objections to claims 5-7, 18 and 30 be removed.

The Examiner rejected claims 12-16 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular the Examiner stated:

It is unclear from the specification *how* the waveform based correction analysis (WCA) temporally segregates the mean hemodynamic response (as depicted by reference number 914) into early and late phases/phase components (as depicted by reference numerals 918 and 920). See p 88 lines 22 – p. 89 line 5 of specification.

With respect to the enablement requirement of 35 U.S.C. §112, first paragraph, the test for enablement is whether the specification has enabled a person skilled in the technical field to which the application relates to make the invention and whether the specification makes clear how the invention is to be carried out in the particular field of utility. In re Naquin 158 U.S.P.Q. 317 (CCPA 1968). A reasonable amount of experimentation is permissible to enable making and/or using of the invention without resulting in failure to satisfy the enablement requirement of §112. In re Miller, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971).

The Examiner has apparently taken the position that segregating data temporally (claim

12), segregating data temporally into a plurality of phases (claim 13), temporally segregating into an early phase waveform and a late phase waveform (claim 14), and correlating pixels from regions in the CNS to distinct waveforms which correspond to at least one of an early phase waveform and a late phase waveform (claims 15 and 16) are not enabled by the specification. Applicants respectfully traverse this rejection.

Claim 12 recites "... data obtained from central nervous system activity is segregated temporally." Numerous examples of segregating data temporally are shown and described throughout the specification. For example, Figs. 8B and 8D and the accompanying written descriptions at page 78 line 24 through page 79 line 23 and page 79 line 34 through page 80 line 34 show and describe data which is segregated temporally.

Support for Claim 13 can be found in the specification at page 91 line 2 through page 91 line 17. Support for Claim 14 can be found at page 88 line 30 through page 89 line 5 and further at page 90 line 27 through page 90 line 32. Support for Claims 15 and 16 can be found at page 91 line 5 through page 91 line 17 and at page 92 line 2 through page 92 line 21.

The Examiner seems to imply that it is necessary to explain how the WCA process works in order to enable claims 12-16. The WCA process is clearly described in a number of locations throughout the specification including at: page 51, line 32 through page 52, line 16 and page 91, line 2 through page 92, line 21. Applicants would also like to point out that waveform based correlation (WCA) is well known in the art and that the use of WCA itself is well within the level of one of ordinary skill in the art. Thus, Applicants do not agree that it is necessary to explain the details of WCA operation to enable claims 12-16. This point is even more compelling when one considers that as stated in the specification *at least* on page 44 lines 17-21, a number of statistical mapping procedures, other than WCA, are currently available for post-hoc analysis.

Accordingly, in view of the above, Applicants respectfully request that the Examiner

withdraw the rejection of claims 12-16 under 35 U.S.C. §112, first paragraph.

The Examiner rejected claims 1-30 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have amended claims 1-30 to address the rejections under 35 U.S.C. §112, second paragraph.

With respect to claim 1, the Examiner states: "Claim 1 is drawn to a method for measuring brain activity, however, no measuring step has been set forth. Applicant's have amended claim 1 to recite "A method for processing brain activity signals ... comprising...."

Also with respect to claim 1 the Examiner stated that "...the correlating step is incomplete in that it is unclear what the signals in a brain region are being correlated with." Applicants have amended claim 1 to recite "...correlating the signals ... to a type of pain" Thus, claim 1 is now clear and definite with the meaning of 35 U.S.C. §112 second paragraph.

With respect to claim 26, the Examiner stated that the element designations conflict with the element designations of claim 23. Applicants have deleted the element designations in claim 26 and thus claim 23 is now clear and definite.

With respect to claim 29, the Examiner stated that the phrase "the treatment" lacks antecedent basis. Applicants have amended claim 29 to depend from claim 28 which recites "a treatment" and thus provides antecedent basis for "the treatment" recited in claim 29. Thus claim 29 is now also clear and definite.

Accordingly, Applicants submit that claims 1-30 are clear and definite within the meaning of 35 U.S.C. §112, second paragraph.

The Examiner rejected claims 1-3, 5-7, 9, 10, 19, 20 and 22-30 under 35 U.S.C. §102(b) as being anticipated by "Acute Effects of Cocaine on Human Brain Activity and Emotion" by

Breiter et al. (hereinafter Breiter).

Breiter discloses the investigation of brain circuitry mediating cocaine-induced feelings of euphoria and craving. Breiter does not disclose pain assessment as called for in claim 1.

Claim 1 calls for localizing signals to specific anatomical and functional CNS regions which participate in reward/aversion functions ... correlating the signals in a reward/aversion brain region to a type of pain ... and interpreting the correlation results.

To sustain a rejection under 35 U.S.C. §102(b) a single reference must disclose each and every element of the claimed invention. Accordingly, since Breiter fails to disclose or suggest localizing the signals to specific anatomical and functional CNS regions which participate in reward/aversion functions, correlating the signals to a type of pain, and interpreting the correlation results as called for in claim 1, claim 1 is patentably distinct over Breiter.

Claims 2, 3, 5-7, 9, 10, 19, 20, and 22-30 each depend from and thus include the elements of claim 1. Thus, claims 2, 3, 5-7, 9, 10, 19, 20 and 22-30 are also patentably distinct over the cited reference generally for the reasons discussed above in conjunction with claim 1.

Accordingly, the rejection of claims 1-3, 5-7, 9, 10, 19, 20, and 22-30 under §102(b) as being anticipated by Breiter may be withdrawn.

The Examiner rejected claims 4, 8 and 21 under 35 U.S.C. §103(a) as being unpatentable over Breiter.

Claims 4, 8, and 21 depend from and thus include the elements of claim 1. Thus, Applicants submit that claims 4, 8 and 21 are patentably distinct over Breiter since Breiter neither describes nor suggests "...localizing signals to specific anatomical and functional CNS regions which participate in reward/aversion functions ... correlating the signals in a

reward/aversion brain region to a type of pain in the subject ... and interpreting the correlation results" as called for in claims 4, 8 and 21. Indeed, Breiter does not discuss pain assessment at all. Accordingly, the rejection of claims 4, 8 and 21 under §103(a) is believed to have been overcome.

The Examiner rejected claims 11-18 under 35 U.S.C. §103(a) as being unpatentable over Breiter in view of U.S. Patent No. 6,073,041 to Hu et al. (hereinafter Hu).

Claims 11-18 depend from thus include the elements of claim 1. Claim 1 includes the steps of localizing the signals to specific anatomical and functional CNS regions which participate in reward/aversion functions, correlating the signals to a type of pain, and interpreting the correlation results. Neither Breiter nor Hu, taken alone or in combination, disclose or suggest localizing the signals to specific anatomical and functional CNS regions which participate in reward/aversion functions, correlating the signals to a type of pain, and interpreting the correlation results. As indicated above, Breiter does not discuss pain assessment at all. Additionally Hu, which is directed to an improved FMRI method, does not cure this deficiency in the teaching of the primary reference. Therefore claims 11-18, are believed allowable over Breiter in view of Hu.

Applicants have added new Claims 39-44. Applicants assert that the additional claims are supported by the specification and that no new matter has been added by the additional claims.

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In view of the above, the Examiner's objections and rejections are believed to have been overcome, placing claims 1-30 and 39-44 in condition for allowance, and reconsideration and allowance thereof is respectfully requested. The Examiner is respectfully invited to telephone the undersigning attorney if there are any questions regarding this Amendment or this application.

The Assistant Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0845.

Respectfully submitted,
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Appendix:

The attached sheets of drawings includes changes to FIGs. 2C, 3, and 11D in both replacement sheets and annotated sheets showing changes.

Attachments: Replacement Sheets

Annotated sheets Showing Changes